REMARKS

Reconsideration of this application, as amended, is respectfully requested. Claims 1-109 stand rejected. Claims 6, 17-19, 39, 51-53, and 76-78 have been amended. Claim 46 has been canceled. Claims 110-112 have been added. Thus claims 1-45 and 47-112 are pending in this case.

Support for the amended and added claims can be found in the application as originally filed. For instance, the specification at page 30, line 31 through page 33, line 24 discloses potential second foreign genes which may be used in this invention to confer insect resistance to the transgenic poinsettia plant. Use of media containing NH_4^+ and/or NO_3^- is disclosed, for example, in the Tables on pages 19, 21, 24, and 26. The use of an osmotic pressure increasing agent is disclosed on p. 15, lns. 35-37. The use of *Agrobacterium tumefaciens*, electroporation, and micro-projectile delivery for introduction of vectors is disclosed on p. 10, ln. 37, to p. 11, ln. 15. Accordingly, no new matter has been added to the application.

Rejection of claims 17-19, 45-46, 51-53 and 76-78 under 35 U.S.C. § 112, 2nd ¶

The Examiner rejected Claims 17-19, 45-46, 51-53 and 76-78 under 35 U.S.C. § 112, 2nd ¶, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 17, 56 and 76 have been amended to clarify that disease is not caused by insects. Claims 18-19, 52-53, and 77-78 have been amended in the manner suggested by the Examiner. Claim 46 has been deleted because it was a duplicate of claim 45.

Rejection of claims 6-96, 98-100, 102-103, 105-106 and 108-109 under 35 U.S.C. § 112, 1st ¶

Claims 6-96, 98-100, 102-103, 105-106 and 108-109 stand rejected under 35 U.S.C. § 112, 1st ¶, as not enabling. The rejection asserted that the specification is enabling only for transgenic Poinsettia plants produced by particle bombardment, whereas "the claims are broadly drawn to any method of producing transgenic plants including *Agrobacterium*-mediated transformation, electroporation, microinjection, polycation incubation of protoplasts, etc." As evidence, it was argued that Follansbee *et al.* were unable to recover whole *Euphorbia* plants following *Agrobacterium*-mediated transformation. Furthermore, it was argued that other transformation techniques require protoplasts or single cells, and techniques for producing whole plants from such plant tissue are not available for Poinsettia. The applicants respectfully traverse.

It is first noted that independent claims have been limited to vector delivery by co-incubating callus tissue with *Agrobacterium tumefaciens*, by microprojectile-mediated delivery of the vector into the callus, or by electroporation. The examiner is in agreement with the applicants that microprojectile bombardment is enabled. Thus, the only remaining issue in view of the amendments made herein is enablement with regard to *Agrobacterium tumefaciens* and electroporation.

In support of the rejection, the Examiner cited Follansbee *et al.*, who were unable to recover whole *Euphorbia* plants following *Agrobacterium*-mediated transformation. Follansbee *et al.* used *Agrobacterium* rhizogenes, however, and not *Agrobacterium* tumefaciens, as presently disclosed and claimed. The difference is significant because *Agrobacterium rhizogenes* systems are designed for obtaining transgenic roots, not whole plants. *Agrobacterium tumefaciens* systems, on the other hand, have been developed to obtain whole plants, such as presently

disclosed and claimed. Accordingly, those skilled in the art not only would not consider Follansbee *et al.*'s work with *Agrobacterium rhizogenes* indicative of the likely outcome with *Agrobacterium tumefaciens* systems, they would in fact expect successful transformation and obtainment of whole transgenic plants with *Agrobacterium tumefaciens*.

In addition, because the teachings of Follansbee *et al.* are not relevant to the *Agrobacterium tumefaciens* system, there remains no evidence or scientific reasoning of record that would suggest the *Agrobacterium tumefaciens* system would not function as disclosed and claimed, as required to sustain an enablement rejection. *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) ("[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.").

With regard to electroporation, the applicants submit herewith two scientific journal articles (Xu *et al.*, *Plant Cell Reports* **13**, 237-242 (1994) & D'Hallui *et al.*, *Plant Cell* **4**, 1495-1505 (1992)), both of which support the use of electroporation in the presently claimed methods.

In view of the foregoing amendments and remarks, the Applicants respectfully request reconsideration and withdrawal of this § 112, 1st ¶, rejection.

Rejection of claims 1-109 under 35 U.S.C. § 112, 1st ¶

Claims 1-109 stand rejected under 35 U.S.C. § 112, 1st ¶, as lacking enablement for other than the particular media recited. The applicants respectfully traverse this rejection.

The applicants first note that the claims have been amended to recite several media components noted by the Examiner. In addition, the claims recite specific media types (*e.g.*, callus induction media, embryo induction media, developmental media, etc.), which are well known and commonly used by those skilled in the art.

The present inventors discovered a method that for the first time permits transformation and subsequent regeneration of transgenic poinsettia plants from tissue culture; prior art techniques were incapable of this. This method, with all its critical elements distinguishing it from the prior art, is recited in the present claims. It is respectfully submitted that one of ordinary skill in the art could employ the recited method to practice the full scope of the claimed invention by following the teachings of the specification and using no more than routine experimentation and common knowledge in the art.

The rejection fails to provide evidence or scientific reasoning why the full scope of the claimed method is not enabled. Rather, the rejection stated in view of the broad scope of the claims, obtainment of whole poinsettia plants from tissue culture was unpredictable given the genotype-dependent techniques available and the recalcitrance of the transformed *Euphorbia* of Follansbee *et al.* The applicants first note that a broad scope is in itself insufficient basis for a non-enablement rejection.

Second, the reasoning and evidence of the rejection is relevant (if at all[1]) only to prior art techniques. While obtainment of whole poinsettia plants from tissue culture may have been unpredictable in the prior art, it is not if one employs the presently claimed method. For instance, at page 15, line 14 *et seq.*, the specification states, "A preferred approach, however, is to use the modifications of the Preil method, as described herein, which provides a genotype-

independent method of producing large quantities of somatic embryos which can be used to regenerate plants." The rejection fails to specify why the presently claimed invention, with its modifications of the prior art techniques, is unpredictable. General assertions of unpredictability and potential difficulties are insufficient to support a rejection under § 112, 1st ¶; the evidence or reasoning must be particularized and definite, directed at the claimed invention, not broad and general. *In re Chilowsky*, 229 F.2d 457, 462 (C.C.P.A. 1956). The applicants respectfully submit that once one employs the modifications to prior art techniques that are recited in the present claims, all unpredictability is eliminated, and the ordinary artisan can routinely obtain transgenic poinsettia plants from tissue culture.

In view of the foregoing, therefore, the applicants respectfully request reconsideration and withdrawal of this § 112, 1st ¶, rejection.

Rejection of claims 1-4, 97, 101, 104 and 107 under 35 U.S.C. § 102(a)

Claims 1-4, 97, 101, 104 and 107 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Lee *et al.* The applicants first note that no basis for this rejection was provided in the Office Action.

More substantively, however, the method disclosed by Lee *et al.* teaches that "the reddish epidermal callus was selected and subcultured back to the *same medium*." (emphasis added) Therefore, the medium used in culturing stem sections was the same as that used for subculturing the reddish epidermal callus. Then the globular to heart staged embryos were subcultured on hormone free medium.

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[1] As noted previously, since Follansbee *et al.* taught the *Agrobacterium rhizogenes* system and the present claims recite *Agrobacterium tumefaciens*, Follansbee *et al.* is no loner relevant to the present claims.

In Claims 1 and 101, by contrast, the tissue explants (*i.e.*, stem sections) are cultured on callus induction medium, while the reddish epidermal callus is cultured on a different medium, the embryo induction medium. These are two different media with different components. The embryogenic callus is then subcultured on a developmental medium, and then the globular to heart-shaped embryos are subcultured on maturation medium, which is not hormone free.

The methods of Claims 1 and 101 are clearly different from those described in Lee *et al.* Claims 1 and 101 required different steps and different medium than that disclosed in Lee *et al.* Therefore, Claims 1 and 101 are not anticipated because each and every element of these claims were not disclosed by Lee *et al.*

Because Claims 2-4 and 97 contain all of the limitations of Claim 1, they also are not anticipated by Lee *et al.* Because Claims 104 and 107 contain all of the limitations of Claim 101, they also are not anticipated by Lee *et al.*

In view of the foregoing, therefore, the applicants respectfully request reconsideration and withdrawal of this § 102(a) rejection.

Rejection of claims 101 and 107 under 35 U.S.C. § 102(b)

Claims 101 and 107 stand rejected under 35 U.S.C. 102(b) as being anticipated by Preil (1994). Preil, however, fails to teach, *inter alia*, subculturing reddish epidermal callus to NH_4^+ and/or NO_3^- containing embryo induction medium. The applicants have found that reddish epidermal callus tissue are particularly preferred target for transformation (specification page 16, lines 12-17). Absent a teaching of these recited elements, Preil cannot anticipate the present claims.

Rejection of claims 1, 101, 104, and 107 under 35 U.S.C. § 102(b)

Claims 1, 101, 104 and 107 stand rejected under 35 U.S.C. 102(b) as being anticipated by Nataraja (1975). Nataraja, however, fails to teach, *inter alia*, subculturing reddish epidermal callus to NH_4^+ and/or NO_3^- containing embryo induction medium. The applicants have found that reddish epidermal callus tissue are particularly preferred target for transformation (specification page 16, lines 12-17). Absent a teaching of these recited elements, Nataraja cannot anticipate the present claims. and, therefore, cannot anticipate the present claims.

Rejection of claims 1-109 under 35 U.S.C. § 103(a)

Claims 1-37, 39-71 and 73-109 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Cheetham *et al.* (1996) taken with Miki et al, Preil (1994) and Nataraja. Claims 1-109 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Miki *et al.* taken with Preil (1994) and Nataraja. For the following reasons, the applicants respectfully traverse these rejections.

None of the cited reference teach, suggest, or even contemplate, *inter alia*, culturing or subculturing reddish epidermal callus to or on NH_4^+ and/or NO_3^- containing embryo induction medium. The applicants have found that reddish epidermal callus tissue are particularly preferred target for transformation (specification page 16, lines 12-17). Absent a suggestion or motivation to culture or subculture reddish epidermal callus tissue, the combinations of recited references cannot render the claimed invention obvious.

Furthermore, as previously noted by the Examiner, "[obtainment] of whole poinsettia plants from tissue culture is unpredictable, given the highly genotype-dependent techniques

available at the time of the invention and the recalcitrance of transformed *Euphorbia* cells to produce whole plants." Given this unpredictability, there could not have been a reasonable expectation of successfully making and using the presently claimed method. For this reason, too, the claimed methods cannot be obvious.

Furthermore, the claimed method is genotype-independent, which is not suggested in the prior art.

For all of the foregoing reasons, therefore, the applicants respectfully request reconsideration and withdrawal of these § 103 rejections.

If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Respectfully submitted,

Date: January 6, 2000

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